PATENT



ppl No.:

Chroboczek et al.

09/530,560

Confirmation No.: 2330 Group Art Unit: 1636

D. Guzo

Filed: For:

May 2, 2000 Examiner: TRANSFECTING PEPTIDE VECTOR, COMPOSITION CONTAINING

SAME AND THEIR APPLICATIONS

Commissioner for Patents Washington, DC 20231

TECH CENTER 1600/2900

ELECTION

In response to the requirement for restriction mailed July 2, 2002, Applicants elect the peptide vector comprising:

- a segment of an NLS sequence including SEQ ID NO: 2 (X₀KRAR) in which X₀ represents an alanine (A),
- a hydrophobic sequence consisting of SEQ ID NO: 7 in which X₁ represents LSTS (SEQ ID NO: 10) and X₂ represents EDES (SEQ ID NO: 16), and
 - a polymeric sequence of basic amino acids.

This election is made with traverse. Applicants submit that the peptide vectors as claimed relate to a single inventive concept, for the reasons set forth more fully below. Therefore, Applicants request reconsideration and withdrawal of the requirement for restriction.

The subject matter of claims 1 and 2 is a peptide vector comprising a transfecting peptide derived from the fibre of an adenovirus, comprising:

- 1. a segment of an NLS chosen from a segment of an adenovirus fibre (SEQ ID NO: 1 to 6) or a segment of the SV40 virus VP3 protein (SEQ ID NO: 24),
- 2. a hydrophobic sequence derived from an adenovirus fibre presenting the sequence X_1 - $F(D/N)PVYPY-X_2$ (SEQ ID NO: 7-8), said vector also comprising or being associated to:
- 3. a polymeric sequence of basic amino acids or a cationic polymeric sequence or a polyalcohol.

Claims 1 and 2 define alternatives according to the so-called Markush practice.

According to Section (f)(i)(B)(1) of Annex B of the Administrative instructions under the PCT which is cited by the Examiner, as regards the interpretation of Rule 13.2 PCT in the situation wherein a single claim defines alternatives, Unity of Invention shall be considered to be

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satisfied when a common structure i.e. <u>a significant structural element is shared by all of the alternatives</u>.

According to Section (f)(ii) of the same Annex B "significant structural element is shared by all alternatives" refers to cases where the compounds may have in common only a small portion of their structures (which may be a single component or combination of individual components linked together), providing that the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art.

The claimed alternatives as claimed in claims 1 and 2 fulfill the requirements of Rule 13.2 PCT for the following reasons.

1) The claimed alternatives share a common structural element

The claimed vectors have in common a portion of their structure which is a combination of an NLS sequence linked to an hydrophobic sequence presenting the motif X_1
[F(D/N)PVYPY[- X_2] which is derived from an adenovirus fibre; this common structural element is illustrated by figure 7.

Thus the claimed alternatives share a common structural element.

2. The claimed alternatives share a significant structural element

It will be seen from the present International Application, for example from Table II page 19, that the hereabove defined common structural element (NLS sequence linked to an hydrophobic sequence presenting the motif X_1 -[F(D/N)PVYPY]- X_2) solves the problem of the invention, i.e. to find a composition capable of efficiently transfecting eukaryotic cells, in the absence of liposomes and of the treatment of cells.

Thus the common structural element shared by the alternatives is <u>a significant structural</u> <u>element.</u>

3. The claimed alternatives share a structurally distinctive portion in view of the prior art.

The hereabove defined common structural element (NLS sequence linked to an hydrophobic sequence presenting the motif X_1 -[F(D/N)PVYPY]- X_2) is novel and not obvious in view of the prior art which uses different transfection peptides:

- a cationic polymer, a basic polymer and an NLS sequence (International Application WO 96/25508),

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- a cationic lipid and an acidic peptide (International Application WO 97/30170),

- a fusion protein consisting of a cellular factor and a basic polycationic peptide (European Application EP 0 544 292),

- a peptide representing a membrane receptor ligand, a NLS sequence and a basic peptide (International Application WO 94/23751),

- a polymer of basic amino acids and an NLS sequence derived from the SV40 T antigen or the adenovirus Ela or Elb proteins, linked by a neutral amino acid binge sequence (International Application WO 95/31557), or

- an adenoviral complex (12 pentons or 12 penton bases) and an attachment peptide derived from the N-terminal region of the adenovirus fibre, comprising a carboxyterminal polylysinc or a polyarginine (International Application WO 97/18317).

Thus, the claimed alternatives share a significant structural element which is distinct from the prior Art.

Therefore, the claimed alternatives meet the requirement of Unity of invention (Rule 13.2 PCT), according to Section (f)(i)(B)(1) and (ii) of Annex B of the Administrative instructions under the PCT.

Consequently, the vectors as claimed in claim 1 and claim 2 form a single general inventive concept (Rule 13.1 PCT).

Respectfully submitted,

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